REMARKS

The specification has been amended to insert the application number of the companion application identified on page 10. It is submitted that these amendments do not constitute new matter and their entry is requested.

Claims 4, 9, 12, 13, 18 and 21 have been canceled. Claims 1, 7, 10, 16, 19, 22, 25, 34, 28, 37, 41 and 43 have been amended to obviate the indefiniteness rejection as specified below with respect to this rejection, and in certain instances to change dependencies in view of the canceled claims. In addition, claims 5, 6, 14, 15, 46, 47, 52 and 53 have been amended to change dependencies in view of the canceled claims. Finally, claims 24 and 33 have been amended to delete a superfluous "is." It is submitted that these amendments do not constitute new matter and their entry is requested.

The Examiner has objected to claim 3. It is believed that the amendments to claims 1 and 3 obviate this objection.

The Examiner has rejected claims 44-55 under 35 USC §112, first paragraph for lack of written description. The Examiner contends that Applicants have not provided a written description of the cultures and plants produce by the claimed method. It is submitted that the Examiner is in error in this rejection.

Applicants have invented a method for regenerating transgenic embryogenic pine cells. The method involves the selection of transgenic embryogenic pine cells using a selection medium which contains an agent that is a substance that regulates differentiation of embryos from embryogenic cells. The agent may be ABA, an osmoticum or a gelling agent. Applicants discovered that the presence of this agent in the selection medium allowed for the first time the regeneration of transgenic plants of pine of the genus *Pinus*, especially lines of certain elite genetic backgrounds of Southern yellow pines. The present application contains a written description of this method.

According to the Written Description Guidelines, a patent specification must describe the invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Possession of the claimed invention is shown by describing the claimed invention with all of its limitations using such descriptive means as **words**, structures,

figures, diagrams, and formulas that fully set forth the claimed invention. (emphasis added) Possession may be shown in a variety of ways inlcuding description of an actual reduction to practice. An adequate written description may be shown by any description of sufficient, relevant identifying characteristics so long as a person skiled in the art would recognize that the inventor had possession of the claimed invention.

In the present application, Applicants have clearly conveyed to a skilled artisan what was intended and what was invented. Applicants described **by words** a method for regenerating genetically modified plants of pine of the genus *Pinus* in which an agent that regulates differentiation is used in the selection medium. Applicants provide several species of the agent, including ABA, an osmoticum and a gelling agent. The method, as described, produces a transgenic embyrogenic pine culture, and upon regeneration, a transformed pine plant. Applicants further described an actual reduction to practice of the claimed invention. The specification includes a description of an acutal reduction to practice not only of the method, but also of the tissue culture produced by the method and transformed plants produced by the method. Thus, a skilled artisan can readily recognize that Applicants were in possession of the claimed invention.

Furthermore, the specification describes products produced by the process. These products are described on the basis of product by process language. Product by process language has been approved by the Patent Office and the courts, inlcuding the Federal Circuit. The *Eli Lilly* decision cited by the Examiner did not exclude product by process as a means of claiming subject matter. The specification clearly conveys to a skilled artisan what was invented by describing the method and by showing products, i.e., tissue culture and transformed plants, produced by the process. Thus, a skilled artisan can readily recognize that Applicants were in possession of the claimed invention.

Finally, the Examiner attempts to apply the *Eli Lilly* decision to the facts of the present case by arguing that Applicants failed to describe the genetic material and as a result the specification fails to provide a written description of the claimed invention. However, *Eli Lilly* was concerned with DNA having only a functional definition. The present case is not directed to DNA, but rather to a method for regenerating genetically modified pine plants and to products of this method, namely a tissue culture (which is an intermediate product) and a transformed plant (the final product). Since

Applicants are not claiming any DNA, a description of such is not required by the patent statutes or the case law. Thus, a skilled artisan can readily recognize that Applicants were in possession of the claimed invention.

In view of the above reasons, it is submitted that the specification contains an adequate written description of the claimed invention, i.e., products by process. Withdrawal of this rejection is requested.

The Examiner has rejected claims 1-3, 22-23, 28, 31-32, 37, 40 and 42 under 35 USC §102(b) as being anticipated by Wenck et al. The Examiner contends that Wenck et al. teaches genetically transforming loblolly pine using *Agrobacterium* and selecting the transformed embryogenic lines with kanamycin as the selection agent and using ABA which acts as an agent to regulate differentiation of embryos from embryogenic cells. It is submitted that Wenck et al. does not disclose the elements of the claimed invention and hence cannot anticipate the claimed invention.

Specifically, Wenck et al. discloses *Agrobacterium* transformation of Norway spruce and loblolly pine. In the process disclosed by Wenck et al., embryogenic cultures of Norway spruce or loblolly pine are transformed with *Agrobacterium* by co-colutivation for 2 days, after which the *Agrobacterium* was removed and the cultures washed. See page 408, right column. Stable transformants were selected by plating the washed suspension cultures onto solid medium containing kanaymcin and cultured for three weeks. The selection medium did not contain ABA. The putative transformants were transfered to fresh medium containing the kanamycin selection agent for three weeks culturing two times. The medium did not contain ABA. Alternatively, hygromycin was used as the selection agent. See page 408, right column, last two lines through page 409, left column, first paragraph. After the transformed cells were obtained, they were then plated onto an embyro maturation medium to mature the embryos prior to germination. The embryo maturation medium contained ABA for differentiation of embryos. See page 409, right column. Although Wenck et al. achieved regenerated plants of Norway spruce, no regenerated plants of loblolly pine were achieved. See, page 413, left column fourth line from bottom.

As disclosed in Wenck et al., the ABA was used for differentiation of embryos from transformed cells. The ABA was not used in the medium to select transgenic embryogenic cells.

The transformed cells of Wenck et al. had been selected by kanamycin or hygromycin on medium which did not contain ABA. The present claims are directed to the use of an agent that regulates differentiation of embryos from embryogenic cells in the selection medium. There is no disclosure in Wenck et al. that kanamycin or hygromycin are agents which regulate differentiation of embryos from embryogenic cells. Since Wenck et al. does not disclose the use of an agent that regulates differentiation of embryos from embryogenic cells in the selection medium, it cannot anticipate the presently claimed invention. For these reasons, it is submitted that Wenck et al. does not anticipate the claimed subject matter, and withdrawal of this rejection is requested.

The Examiner has rejected claims 1-23, 28, 29, 31, 32, 37, 38, 40 and 42 under 35 USC §103(a) as being obvious over Wenck et al. in view of Rutter et al. The Examiner contends that Rutter et al. teaches using ABA, PEG and gellan gum in their medium to enhance transformation and regeneration efficiency. It is submitted that Wenck et al. does not disclose the elements of the claimed invention and these elements are not supplied by the secondary reference. Therefore, the cited references cannot not render the claims obvious.

Rutter et al. discloses a process for the somatic embryogensis of conifer species. The process comprising culturing an explant on (or in) a medium to obtain embryogenic tissue, culturing the embyrogenic tissue on (or in) a medium to maintain the embryogenic tissue, culturing the maintained embryogenic tissue on a first embryo development medium to develp a stage 3 somatic embryo, culturing the stage 3 somatic embryo on a second embryo development medium to maintain the stage 3 somatic embyro, separating and partially drying the stage 3 somatic embryo, culturing the paritally dried somatic embryo on germination medium to germinate the embryo, converting the germinated embryos into acclimatized plants and field planting the acclimatized plants. Rutter et al. disclose that the essential elements of the invention is the use of ABA in the first and second development media, and the use of PEG in the first development medium. The ABA and PEG are used as agents to differentiate somatic embryos from embryogenic tissue. Rutter et al. discloses the use of gellan gum as a gelling agent. There is no disclosure of the transformation of confers in Rutter et al., and thus, no disclosure or enhancing transformation efficiency. Since there is no disclosure of transformation, there is no disclosure of selection of transgenic embyrogenic cells. Consequently,

Rutter et al. does not disclose the use of ABA, PEG or gellan gum to select transgenic embryogenic pine cells.

As described above Wenck et al. does not describe the use of an agent that regulates differentiation of embryos from embryogenic cells in a selection medium. Rutter et al. also does not disclose the use of an agent that regulates differentiation of embryos from embryogenic cells in a selection medium. Thus, Rutter et al. does not cure the deficieny of Wenck et al., and the combination of these references does not render the claimed invention obvious. Furthermore, if there was any motivation to combine these references, which Applicants do not believe there is, it would only yield a process in which ABA or PEG is used to differentiate somatic (i.e., mature embryos) from transformed cells. There is no suggestion to use such agents in the selection medium as set forth in the present claims. For these reasons, it is submitted that Wenck et al. and Rutter et al. does not render the claimed subject matter obvious, and withdrawal of this rejection is requested.

The Examiner has rejected claims 1-3, 22-28, 31-37 and 40-43 under 35 USC §103(a) as being obvious over Wenck et al. in view of Levee et al. The Examiner cites Levee et al. for its disclosure of support membranes and layers of medium. It is submitted that Wenck et al. does not disclose the elements of the claimed invention and these elements are not supplied by the secondary reference. Therefore, the cited references cannot not render the claims obvious.

Specifically, as described above Wenck et al. does not describe the use of an agent that regulates differentiation of embryos from embryogenic cells in a selection medium. Levee et al. likewise does not disclose this element of the claimed invention, since its only disclosure relates to the use of a support membrane. Furthermore, if there was any motivation to combine these references, which Applicants do not believe there is, it would only yield a process in which a support membrane is used in a process in which an antibiotic is used as a selective agent and ABA is used to differentiate embryos from transformed cells. Thus, there would be no suggestion of the use of ABA in a selection medium as set forth in the present claims. For these reasons, it is submitted that Wenck et al. and Levee et al. does not render the claimed subject matter obvious, and withdrawal of this rejection is requested.

The Examiner has rejected claims 1-3, 22-28, 30-37 and 39-43 under 35 USC §103(a) as being obvious over Wenck et al. in view of Levee et al. and Rutter et al. Levee et al. and Rutter et al. were cited for the reasons discussed above. It is submitted that Wenck et al. does not disclose the elements of the claimed invention and these elements are not supplied by the secondary references. Therefore, the cited references cannot not render the claims obvious.

Specifically, as described above Wenck et al. does not describe the use of an agent that regulates differentiation of embryos from embryogenic cells in a selection medium. As described above, neither Levee et al. nor Rutter et al. suggest the use of an agent that regulates differentiation of embryos from embryogenic cells in a selection medium. For these reasons, it is submitted that Wenck et al., Levee et al. and Rutter et al. does not render the claimed subject matter obvious, and withdrawal of this rejection is requested.

The Examiner has rejected claims 1, 4, 7, 10, 13, 16, 19, 22, 24, 25, 27, 28, 31, 33, 34, 36, 37, 41 and 43 under 35 USC §112, second paragraph for being indefinite. Applicants initially note that claims are not read with blinders or based on their literal language but are read in view of the knowledge possessed by one skilled in the art. The words of the claims are read in their context, not in isolation, and as a skilled artisan would read them. In this context, the claims and the Examiner's rejection are discussed.

Claim 1 has been amended to incorporate the language of claim 4 and to clarify that the agent is in a medium. Claim 1 has further been amended to indicate that the agent may be a combination of the listed substances as disclosed at page 7, lines 27-28. With respect to the term osmoticum, Applicants direct the Examiner's attention to U.S. Patent No. 6,340,594 which describes the use of osmoticums for the production of desiccation-tolerant gymnosperm embryos. This patent issued from an application filed on 5 December 1997 and evidences the known use of this term in the art. Since the term "osmoticum" is known to a skilled artisan, it is submitted that its use in claim 1 is not indefinite.

Claims 4 and 13 have been canceled.

Claims 7 and 16 have been amended to incorporate claims 9 and 18, respectively.

Claims 10 and 19 have been amended to incorporate claims 12 and 21, respectively.

The Examiner included claims 22 and 31 in the rejection, but did not specify any issue with these claims. Nevertheless, claims 22 and 31 have been amended to specify that that the cells are cultured using a medium containing the agent.

Claims 24 and 33 have been amended to remove a superfluous "is." Claims 24 and 33 recited that the cells are cultured on the support membrane. Hence, it is submitted that it is clear in claims 24, 27, 33 and 36 what is supported.

Claims 25 and 34 have been amended to delete the language "thin film of."

Claims 28 and 37 have been amended to specify that the transformed cells are cultured on a gel medium comprising the agent. However, it is submitted that a skilled artisan would not read the term "in the presence of" as suggested by the Examiner, which is not the conventional use of the term in the art. This remark also applies to claims 22 and.

Claims 41 and 43 have been amended to indicated that the *Agrobacterium* is eradicated from pines cells subjected to *Agrobacterium* transformation. However, it is submitted that a skilled artisan would not have read the original claims directed to transformation of pine cells to call for the eradiction from the face of the Earth as suggested by the Examiner.

It is believed that these amendments and remarks obviate the indefiniteness rejection. Withdrawal of this rejection is requested.

Finally, the Examiner has rejected claims 1-8, 10-11, 13-17, 19-20 and 22-55 for obviousness-type double patenting over claims 1-12, 14, 15, 17, 18, 21, 23, 25, 30, 34, 45, 47,51, 57, and 63-81 of copending application Serial No. 09/973,088 ('088 application). It is submitted that the Examiner is in error in this rejection. The claims of the present invention are directed to the selection of transgenic embyrogenic pine cells using an agent that regulates differentiation of embryos from embyogenic cells. This invention is not described nor claimed in the '088 application. There is nothing in the '088 application which would suggest using an agent that regulates differentiation of embryos from embyogenic cells to select for transgenic embyrogenic pine cells, nor has the Examiner pointed to any teaching in the '088 application for the use of the presently claimed selection agent. Therefore, it is submitted that the present claims are not unpatentable for obviousness-type double patenting over the cited claims of the '088 application.

Finally, Applicants note that an Information Disclosure Statement was filed on 21 May 2002. It would be appreciated if the Examiner would return a copy of the art citation that has been initialed and dated with the next communication.

In view of the above amendments and remarks, it is believed that the claims satisfy the requirements of the patent statutes and are patentable over the cited prior art. Reconsideration of the instant application and early notice of allowance are requested. The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

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Attachments: Marked-Up Copies of Amendments

Marked-up Copy of of Amended Specification - Paragraph 35 on Page 10

[0035] Accordingly, it has been found that the coupling of the ABA concentrations and/or gelling agent manipulations taught for initiation of primary somatic embryogenesis in U.S. Patent No. 5,856,191, with the method for biolistic transformation and selection, described in U.S. patent application Serial No. 09/318,136 filed on 25 May 1999 and New Zealand Patent No. 336149, each incorporated herein by reference, or with the method for Agrobacterium transformation and selection, described in U.S. patent application Serial No. ~~09/~~ 09/973,088 filed concurrently herewith, entitled "Enhanced Transformation and Regeneration of Transformed Embryogenic Pine Tissue" (Attorney Docket No. FSL 2411-110), incorporated herein by reference, yields a marked improvement in the growth of embryogenic cultures during the critical phase of selection.

Marked-up Copy of Amended Specification - Paragraph 36 on Page 10

[0036] Culture of pine embryogenic cells on media containing a lowered gelling agent concentration is facilitated by the use of highly liquid-permeable membrane supports, made from low-absorption fibers such as polyester and other non-cellulosic fibers with similar characteristics described in U.S. patent application Serial No. ~~09/~~ 09/973,088 filed concurrently herewith, entitled "Enhanced Transformation and Regeneration of Transformed Embryogenic Pine Tissue" (Attorney Docket No. 2411-110), incorporated herein by reference.

Marked-up Copy of Amended Claims

1 (amended). A method for regenerating genetically modified plants of pine of the genus *Pinus* selected from the group consisting Southern yellow pines and hybrids thereof, which comprises selecting transgenic embryogenic pine cells using a selection medium comprising ~~in the presence of~~ an agent that regulates differentiation of embryos from embryogenic cells, said agent is selected from the group consisting of abscisic acid (ABA), an osmoticum, a gelling agent and combinations thereof.

3 (amended). The method of claim 1, wherein transformed pine cells are cultured using a medium comprising ~~in the presence of~~ said agent to select said transgenic embryogenic pine cells.

5 (amended). The method of claim 1 ~~4~~, wherein said agent is ABA.

6 (amended). The method of claim 1 ~~4~~, wherein said agent is polyethylene glycol (PEG).

7 (amended). The method of claim 1 ~~4~~, wherein said agent is a gelling agent introduced into the selection medium in ~~larger than normal quantities~~ an amount between about 3% and about 5%.

10 (amended). The method of claim 1 ~~4~~, wherein said agent is a gelling agent introduced into the selection medium in ~~less than normal quantities~~ an amount between about 0.5% and about 1.5%.

14 (amended). The method of claim 3 ~~13~~, wherein said agent is ABA.

15 (amended). The method of claim 3 ~~13~~, wherein said agent is polyethylene glycol (PEG).

16 (amended). The method of claim 3 ~~13~~, wherein said agent is a gelling agent introduced into the selection medium in ~~larger than normal quantities~~ an amount between about 3% and about 5%.

19 (amended). The method of claim 3 ~~16~~, wherein said agent is a gelling agent introduced into the selection medium in ~~less than normal quantities~~ an amount between about 0.5% and about 1.5%.

22 (amended). The method of claim 1, wherein said selection is performed by

culturing pine cells which have been subjected to transformation ~~in the presence of~~ using a transformation medium comprising said agent;

contacting said cells with a selection agent; and

selecting transformed cells.

24 (amended). The method of claim 22, wherein said selection agent is contained in a layer and said cells are cultured on a support membrane ~~is~~ placed over said layer which is placed on a gel medium.

25 (amended). The method of claim 24, wherein said layer is a ~~thin film of~~ liquid medium.

28 (amended). The method of claim 22, wherein said transformed cells are cultured ~~in the presence of said agent which is in said~~ on a gel medium comprising said agent.

31 (amended). The method of claim 3 ~~4~~, wherein said selection is performed by

culturing pine cells which have been subjected to transformation ~~in the presence of~~ using a transformation medium comprising said agent;

contacting said cells with a selection agent; and

selecting transformed cells.

33 (amended). The method of claim 31, wherein said selection agent is contained in a layer and said cells are cultured on a support membrane ~~is~~ placed over said layer which is placed on a gel medium.

34 (amended). The method of claim 33, wherein said layer is a ~~thin film of~~ liquid medium.

37 (amended). The method of claim 31, wherein said transformed cells are cultured ~~in the presence of said agent which is in said~~ on a gel medium comprising said agent.

41 (amended). The method of claim 40 which further includes the eradication of *Agrobacterium* from pine cells subjected to *Agrobacterium* transformation following transformation.

43 (amended). The method of claim 42 which further includes the eradication of *Agrobacterium* from pine cells subjected to *Agrobacterium* transformation following transformation.

46 (amended). A transgenic embryogenic pine culture prepared by the method of claim 3 ~~4~~.

47 (amended). A transgenic embryogenic pine culture prepared by the method of claim 5 ~~13~~.

52 (amended). A transformed pine plant of the genus *Pinus* regenerated from transgenic embyrogenic pine cells selected by the method of claim 3 ~~4~~.

53 (amended). A transformed pine plant of the genus *Pinus* regenerated from transgenic embyrogenic pine cells selected by the method of claim 5 ~~13~~.